

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** (Not for submission under 37 CFR 1.99)

Application Number 10776470  
Filing Date 2004-02-11  
First Named Inventor McBride  
Art Unit 1616  
Examiner Name  
Attorney Docket Number 329532

4/13/07  
ML 10/24/07  
10/24/07

## **U.S. PATENTS**

[Remove](#)

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

[Add](#)

## **U.S. PATENT APPLICATION PUBLICATIONS**

[Remove](#)

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

[Add](#)

## **FOREIGN PATENT DOCUMENTS**

[Remove](#)

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
/ML/	1	JP 03173900	A		1991-07-29	Jacques		<input checked="" type="checkbox"/>
/ML/	2	WO 97/41898			1997-11-13	Griffiths		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

[Add](#)

## **NON-PATENT LITERATURE DOCUMENTS**

[Remove](#)

OCT 04 2005

PTO/SB/08A (07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449-PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 8

**Complete if Known**

Application Number 10/776,470; Confirmation 3576

Filing Date 2/11/2004

First Named Inventor McBride

Art Unit 1616

Examiner Name

Attorney Docket Number 329532

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
/ML/	1	US-5,274,076	12/12/1993	Barbet et al.	
	2	US- 6,096,289	8/2000	Goldenberg	
	3	US- 5,883,894	11/4/1997	Bagshawe et al.	
	4	US- 5,893,762	12-02-1997	Queen et al.	
	5	US- 5,837,242	11-17-1998	Holliger et al.	
	6	US- 6,121,424	9-19-2000	Whitlow et al.	
	7	US- 2002/0006379	1-17-2002	Hansen et al.	
	8	US- 6,126,916	10/3/2000	McBride	
	9	US- 6,077,499	6/20/2000	Griffiths	
	10	US- 6,010,680	1/4/2000	Govindan et al.	
	11	US- 5,959,083	9/28/1999	Bosslet et al.	
	12	US- 5,776,095	7/7/1998	Goldenberg	
	13	US- 5,776,094	7/7/1998	Goldenberg	
	14	US- 5,776,093	7/7/1998	Goldenberg	
	15	US- 5,772,981	6/30/1998	Govindan et al.	
	16	US- 5,753,206	5/19/1998	McBride et al.	
	17	US- 5,746,996	5/5/1998	Govindan et al.	
	18	US- 5,697,902	12/16/1997	Goldenberg	
	19	US- 5,591,828	7/1/1997	Bosslet et al.	
/ML/	20	US- 5,328,679	7/12/1994	Hansen et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/ML/	21	WO 99/66951 A2	12/29/1999	Hansen		
	22	WO 00/34317	6/15/2000	Carr		
	23	WO 9808875	3/5/1998	Bohlen		
	24	WO 9604313	2/15/1996	Goldenberg		
	25	EP 0623675	9/11/1994	Ahrweiler		
	26	IE 921782	12/16/1992	Bosslet		
	27	EP 0511011A	10/28/1992	Randle		
	28	EP 0419387	11/20/1996	Barbet		
/ML/	29	EP 0517024 A2	12/9/1992	Bosslet		

Examiner  
Signature

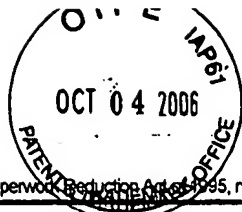
/Marialouisa Lao/

Date  
Considered

10/26/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



PTO/SB/08B(07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

2

of

8

**Complete if Known**

Application Number	10/776,470; Confirmation 3576
Filing Date	2/11/2004
First Named Inventor	McBride
Art Unit	1616
Examiner Name	
Attorney Docket Number	329532

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/ML/	30	BOISFERON, Hillairet de et al., "Enhanced Targeting Specificity to Tumor Cells by Simultaneous Recognition of Two Antigens" Bioconjugate Chem. 2000 11, 252-460	
	31	PLUCKTHUN et al., "New protein engineering approaches to Multivalent and bispecific antibody fragments," Immunotechnology 3 (1997) 83-105	
	32	PACK et al., "Tetavalent Miniantibodies with High Avidity Assembling in Escherichia Coli," J. Mol. Biol. (1995) 246, 28-34	
	33	SHARKEY et al., "A Universal Pretargeting System for Cancer Detection and Therapy Using Bispecific Antibody," Cancer Research 63, 354-363 (Jan. 15, 2003)	
	34	KARACAY et al., "Studies on a Humanized anti-CEA x murine anti-(In- DTPA) bispecific antibody construct for radioimmunotherapy of CEA-positive tumors," Proceedings of the American Association for Cancer Research Annual Meeting, Vol. 40, p 644 (March 1999).	
	35	KARACAY et al., "Pretargeting studies with a humanized anti-CEA X Murine anti-(In- DTPA) bispecific antibody construct and Tc-99m/Re-188 labeled peptide," Journal of Nuclear Medicine, Vol. 40, No. 5 Suppl., p. 225 (May 1999).	
	36	GAUTHEROT et al., "Delivery of Therapeutic doses of Radioiodine using Bispecific antibody-targeted bivalent Haptens," Journal of Nuclear Medicine, Vol. 39 (11), pp 1937-43 (Nov. 1998)	
	37	BODERE et al. "Phase I/II trial of two-step radioimmunotherapy in medullary thyroid cancer (MTC) using bispecific anti-CEA/anti-DTPA-in antibody and iodine-131-labeled bivalent hapten," Journal of Nuclear Medicine, Vol. 39, No. 5 Suppl., p 246 (May 1998)	
	38	BARDIES et al. "Bispecific antibody and Iodine-131-labeled bivalent hapten dosimetry in patients with medullary thyroid or small-cell lung cancer," Journal of Nuclear Medicine, Vol. 37, pp 1853-1859 (Nov. 1996)	
	39	KRAEBER-BODERE et al., "Bispecific antibody and bivalent hapten radioimmunotherapy in CEA-producing medullary thyroid cancer xenograft," Journal of Nuclear Medicine, Vol. 40 (1), pp. 198-24 (Jan. 1999)	
/ML/	40	HOSONO et al., "Biodistribution and dosimetric study in medullary thyroid cancer xenograft using bispecific antibody and Iodine-125-labeled bivalent hapten," Journal of Nuclear Medicine, Vol. 39 (9), pp 1608-13 (Sept. 1998)	

Examiner  
Signature

/Marialouisa Lao/

Date  
Considered

10/26/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Under the Paperwork Reduction Act of 1995, no person <sup>18</sup> <sup>19</sup> is required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

Sheet	3	of	8
-------	---	----	---

**Complete if Known**

Application Number	10/776,470; confirmation 3576
--------------------	-------------------------------

**Filing Date** : 2/11/2004

**First Named Inventor** . McBride

Art Unit 1616

**Examiner Name**

Attorney Docket Number 329532

## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
/ML/	41	US-5,274,076	12/28/1993	Barbet et al.	
	42	US- 5,128,119	7/7/1992	Griffiths	
	43	US- 5,101,827	4/7/1992	Goldenberg	
	44	US- 4,735,210	4/5/1988	Goldenberg	
	45	US- 4,468,457	8/28/1984	Goldenberg et al.	
	46	US- 4,737,453	4/12/1988	Primus	
	47	US- 4,792,521	12/20/1988	Shochat	
	48	US- 4,971,792	11/20/1990	Steplewski et al.	
	49	US- 5,078,998	1/7/1992	Bevan et al.	
	50	US- 5,183,756	2/2/1993	Schlom	
	51	US- 5,25,541	7/6/1993	Hackett et al.	
	52	US- 5,469,854	11/28/1995	Unger et al.	
	53	US- 5,716,595	2/10/1998	Goldenberg	
	54	US- 5,837,243	11/17/1998	Deo et al.	
	55	US- 5,851,527	12-22-1998	Hansen	
	56	US- 4,863,713	9-5-1989	Goodwin et al.	
	57	US- 5,502,037	3-26-1996	Kondratyev	
	58	US- 5,534,756	7-9-1998	Huston, et al.	
	59	US- 6,187,284	2-13-2001	Griffiths	
/ML/	60	US- 5,503,987	4-2-1998	Wagner	

## FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner  
Signature**

/Marialouisa Lao/

Date Considered

10/26/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).<sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***



PTO/SB/08B(07-05)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 4 of 8

**Complete if Known**

Application Number	10/776,470; Confirmation 3576
Filing Date	2/11/2004
First Named Inventor	McBride
Art Unit	1616
Examiner Name	
Attorney Docket Number	329532

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/ML/	62	KRANENBORG et al., "Development and characterization of anti-renal cell carcinoma x antichelate bispecific monoclonal antibodies for two-phase targeting of renal cell carcinoma," Cancer Research, Vol. 55 (23 Wuppl.), pp 5864S-5867S (Dec. 1, 1995)	
	63	KRANENBORG et al., "Two-Step radio-immunotargeting of renal-cell carcinoma xenografts in nude mice with anti-renal-cell-carcinoma X anti-DTPA bispecific monoclonal antibodies," International Journal of Cancer, Vol. 75 (1), pp 74-80 (Jan. 5, 1998)	
	64	GAUTHEROT et al., "Therapy for colon carcinoma xenografts with bispecific antibody-targeted, iodine-131-labeled bivalent hapten," Cancer, Vol. 80, No. Supp. 12, pp 2618-2623 (Dec. 15, 1997)	
	65	BOSSLET et al., "Generation of bispecific monoclonal antibodies for two phase radioimmunotherapy," British Journal of Cancer, Vol. 63/5, pp 681-686 (1991)	
	66	MANETTI et al., "Intracellular uptake and catabolism of anti-IgM antibodies and bi-specific antibody-targeted hapten by B-lymphoma cells," Int. J. Cancer, Vol. 63(2), pp 250-6 (1995)	
	67	BARBET et al., "Radiolimmunotherapy of LS174T colon carcinoma in nude mice using an iodine-131-labeled bivalent hapten combined with an anti-CEAX anti-indium-DTPA bispecific antibody," Tumor Biology, Vol. 18, No. Suppl. 2, p 31 (Sept. 1997)	
	68	MCGUINNESS et al., "Phage diabody repertoires for selection of large number of bispecific antibody fragments," Nature Biotechnology, 14:1149-1154 (1996)	
	69	ALT, et al., "Novel tetravalent and bispecific IgG-like antibody molecules combining single chain diabodies with the immunoglobulin gamma-1 or CH3 region," FEBS LETT, 454: 90-94 (1999).	
	70	OLAFSEN et al., "IgM secretory tailpiece drives multimerisation of bivalent scFv fragments in eukaryotic Cells," Immunotechnology, 4(2):141-153 (1998)	
	71	KIPRIYANOV et al., "Bispecific tandem diabody for tumor therapy with improved antigen binding and pharmacokinetics," J. Mol. Biol., 293(1):41-56 (1999).	
/ML/	72	HAWKINS, et al., "Delivery of Radionuclides to Pretargeted Monoclonal Antibodies Using Dihydrofolate Reductase and Methotrexate in an Affinity System," Cancer Research, Vol. 53, pp 2368-2373, May 1993	

Examiner Signature	/Marialouisa Lao/	Date Considered	10/26/2007
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

OCT 04 2006  
PATENT & TRADEMARK OFFICE

Approved for use through 07/31/2008. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

**(Use as many sheets as necessary)**

Sheet	5	of	8
-------	---	----	---

**Complete if Known**

Application Number	10/776,470; Confirmation 3576
--------------------	-------------------------------

<b>Filing Date</b>	2/11/2004
--------------------	-----------

First Named Inventor	McBride
----------------------	---------

Art Unit	1616
----------	------

**Examiner Name**

Attorney Docket Number	329532
------------------------	--------

[illegible][illegible]

/Marialouisa Lao/

10/26/2007

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

***If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.***



PTO/SB/08B(07-05)

Approved for use through 07/31/2008. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

6

of

8

**Complete if Known**

Application Number	10/776,470; confirmation 3576
Filing Date	2/11/2004
First Named Inventor	McBride
Art Unit	1616
Examiner Name	
Attorney Docket Number	329532

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/ML/	77	GOODWIN, et al., "Pre-Targeted Immunoscintigraphy of Murine Tumors with Indium-111-Labeled Bifunctional Haptens," J. Nucl. Med., Vol. 29, pp 226-234, 1998	
	78	STICKNEY, et al., "Bifunctional Antibody: A binary Radiopharmaceutical Delivery System for Imaging Colorectal Carcinoma," Cancer Research, Vol. 51, pp 6650-6655, December 15, 1991.	
	79	GAUTHEROT, et al., "Therapy for Colon Carcinoma Xenografts with Bispecific Antibody-Targeted, Iodine-131-Labeled Bivalent Hapten," Cancer Supplement, Vol. 80, pp 2618-2623, 1997	
	80	BARBET et al., "Radioimmunodetection of Medullary Thyroid Carcinoma Using Indium-111 Bivalent Hapten and Anti-CEA X Anti-DTPA-Indium," The Journal of Nuclear Medicine, Vol. 39, No. 7, July 1998.	
	81	KRANENBORG, et al. "Development and Characterization of Anti-Renal Cell Carcinoma x Antichelate Bispecific Monoclonal Antibodies for Two-Phase Targeting of Renal Cell Carcinoma," Cancer Research Supplement, Vol. 55, pp 5864s-5867s, December 1, 1995	
	82	CHATZIOANNOU, A., et al., "MICROPET 1: performance Evaluation of a Very High Resolution pet Scanner Proceedings of the 44 <sup>th</sup> Annual Meeting Scientific Papers, Vol. 38, No. 5, May 1997 Supplement	
	83	SCHUHMACHER, et al., "Multistep Tumor Targeting in Nude Mice Using Bispecific Antibodies and a Gallium Chelate Suitable for Immunoscintigraphy with Positron Emission Tomography," Cancer Research, Vol. 55, pp 115-123, January 1, 1995.	
	84	SHARKEY, et al., "Development of a Streptavidin-Anti-Carcinoembryonic Antigen Antibody, Radiolabeled Biotin Pretargeting Method for Radioimmunotherapy of Colorectal Cancer. Studies in A Colon Cancer Xenograft Model," Bioconjugate Chemical, Vol. 8, No. 4, 1997	
	85	ARANO, YASUSHI, et al., "Reassessment of Diethylenetriaminepentaacetic Acid (DTPA) as a Chelating Agent for Indium-111 Labeling of Polypeptides Using a Newly Synthesized Monoreactive DTPA Derivative," J. Med. Chem, Vol 39, pp. 3451-3460, 1996	
	86	BARMAS, A., et al. "Two-Step Strategies for the Diagnosis and Treatment of Cancer with Bioconjugates," Antibody, Immunoconjugates, Radiopharm., Vol. 5, No. 4, pp. 385-395, 1992	
/ML/	87	BOS, EBO S., et al. "In Vitro Evaluation of DNA-DNA Hybridization as a Two-Step Approach in Radioimmunotherapy of Cancer," Cancer Research, Vol. 54, pp. 3479-3486, 1994	

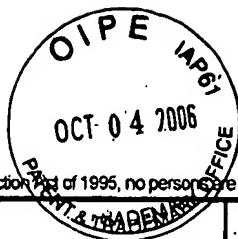
Examiner Signature	/Marialouisa Lao/	Date Considered	10/26/2007
-----------------------	-------------------	--------------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/08B(07-05)

Approved for use through 07/31/2006. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 7 of 8

**Complete if Known**

Application Number	10/776,470; Confirmation 3576
Filing Date	2/11/2004
First Named Inventor	McBride
Art Unit	1616
Examiner Name	
Attorney Docket Number	329532

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/ML/	88	GAUTHEROT, et al., "Radioimmunotherapy of LS174T Colon carcinoma in Nude Mice Using an Iodine-131-Labeled Bivalent Hapten Combined with an Anti-CEA X Anti-indium-DTPA Bispecific Antibody," J. Nucl. Med., Vol. 38, p. 7, 1997	
	89	GREENWOOD, F. C., et al., "The Preparation of 131I-Labelled Human Growth Hormone of High Specific Radioactivity," The Biochemical Journal, Vol. 89, pp. 114-123, 1963	
	90	KANEKO, T., "New Hydrazone Derivative of Adriamycin and Their Immunoconjugates—a Correlation between Acid Stability and Cytotoxicity," J. Bioconjugate Chem., Vol. 2, No. 3, pp. 133-141, 1991	
	91	KARACAY, ET AL., "Experimental Pretargeting Studies of Cancer with a Humanized anti-CEA x Murine anti-[In-DTPA] Bispecific Antidoy Construct and a 99mTc-188 Re-Labeled Peptide," Bioconjugate Chem., Vol. 11, pp. 842-854, 2000	
	92	LOSMAN, M. J., et al., "Generation and Monitoring of Cell Lines Producing Humanized Antibodies," Clin. Cancer Research, Vol. 5, (10 Suppl.) pp. 3101s-3105s, 1999	
	93	PENEFSKY, Harvey S., "A Centrifuged-Column Procedure for the Measurement of Ligand Binding by Beef Heart F," Methods in Enzymology, Part G, Vol. 56, pp. 527-530, 1979	
	94	WANG, SHING-MING, et al., "Specific Activation of Glucuronide Prodrugs by Antibody-targeted Enzyme Conjugates for Cancer Therapy," Cancer Res., Vol. 52, pp. 4484-4491, 1992	
	95	DE JONGE, JAN, et al., "Production and Characterization of Bispecific Single-Chain Antibody Fragments," Molecular Immunology, Vol. 32, No. 17/18, pp. 1405-1412, 1995	
	96	BODEN, V., et al., "Preliminary Study of the Metal Binding Site of an Anti-DTPA-Indium Antibody by Equilibrium Binding Immunoassays and Immobilized Metal Ion Affinity Chromatography," Bioconjugate Chem., Vol. 6, pp. 373-379, 1995	
	97	GOLD et al., Cancer Research, 50 8405-8409, 1990	
/ML/	98	VAN SPRIEL, et al., "Immunotherapeutic Perspective for Bispecific antibodies" Immunology Today, 21, 391-396, 2000	

Examiner Signature	/Marialouisa Lao/	Date Considered	10/26/2007
--------------------	-------------------	-----------------	------------

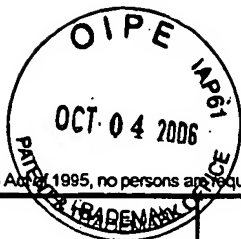
\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.





PTO/SB/088(07-06)

Approved for use through 09/30/2006. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 8 of 8

**Complete if Known**

Application Number	10/776,470; Confirmation 3576
Filing Date	2/11/2004
First Named Inventor	McBride
Art Unit	1616
Examiner Name	
Attorney Docket Number	329532

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/ML/	99	KONTERMANN, Roland E., "Intracellular and Cell Surface Displayed single-chain Diabodies" Journal of Immunological Methods 226 (1999) 179-188	
/ML/	100	DUBEL, S., "Reconstitution of human pancreatic RNase from two separate fragments fused to different single chain antibody fragments: on the way to binary immunotoxins" Tumor Targeting (1999) 4, 37-46 XP009010728	
/ML/	101	HAYDEN, M. "Single-chain mono- and bispecific antibody derivatives with novel biological properties and antitumour activity from a COS cell transient expression system" Therapeutic Immunology, 1994, 1, 3-15	
/ML/	102	YANG "A Genetically Engineered Single-Chain FV/TNF Molecule Possesses the Anti-Tumor Immunoreactivity of FV as well as the Cytotoxic Activity of Tumor Necrosis Factor" Molecular Immunology Vol. 32, No. 12, pp. 873-881, 1995 XP 000653177	
/ML/	103	KARACAY, H., et al., "Pretargeting Studies with a Murine Anti-Colon-Specific Antigen-P (CSAp) X Chimeric Anti-[Indium-DTPA] Bispecific Antibody and Technetium-99m-Labeled Peptide" Cancer Biotherapy and Radiopharmaceuticals, Vol. 15, No. 4, 2000, page 412, XP008065412	
/ML/	104	KARACAY, H., et al., "Experimental Preatargeting Studies of Cancer with a Humanized anti-CEA Murine anti-[Indium-DTPA] Bispecific Antibody Construct and a 99mTc-188Re-Labeled Peptide" Bioconjugate Chem. 2000, 11, 842-854	

Examiner Signature	/Marialouisa Lao/	Date Considered	10/26/2007
--------------------	-------------------	-----------------	------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.